

### REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on May 4, 2004, the Examiner rejected Claims 1 and 9 under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement. The Examiner also rejected claims 1, 4-12, 24 and 26 under 35 U.S.C. § 103(a) as being unpatentable over MUMFORD, LOU, "*Benefits of noni juice may be imagined; \$30 price tag isn't: MUM'S THE WORD*," SOUTH BEND TRIBUNE C1 (Feb. 20, 1998) ("Mumford") in view of BROCK, THOMAS D. ET AL, BIOLOGY OF MICROORGANISM 334 (6<sup>th</sup> ed. 1991)("Brock"), in view of GAGNON, DANIEL J, LIQUID HERBAL DROPS IN EVERYDAY USE 22, 27 (3d. ed. 1997) ("Gagnon"), and further in view of European Patent No. 555,573 A1 (Published Aug. 18, 1993) to Nahir ("Nahir"). Accordingly, Applicant respectfully provides the following.

1. Claim Rejections under 35 U.S.C. § 112, First Paragraph.

The "fundamental factual inquiry [in making a 35 U.S. C. § 112, first para. rejection] is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." See MPEP § 2163(I)(B). Compliance with the written description requirement requires that "each claim limitation . . . be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." See MPEP § 2163(II)(A)(3)(b)(internal quotes omitted).

Claims 1 and 9 stand rejected under 35 U.S.C. § 112, first paragraph ("Section 112") for failing to comply with the written description requirement. The Examiner indicates that the

claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claim invention. Specifically, the Examiner indicated that “[a]lthough Applicants disclosed ‘more than 1 oz.’ in the instant specification, it is deemed that applicant’s are not entitled to limitations which do not have specific support in the specification. It is not entirely clear what Applicants contemplated to be ‘more than 1 oz.’ and therefore, it also cannot be clearly determined if applicant’s intended the scope of ‘more than 1 oz.’ to include ‘3 ozs.’”. Based on this line of reasoning the Examiner concludes that the Applicants did not contemplate the specific use of 3 ounces of noni juice. Applicant respectfully submits that rejected claims 1 and 9 find adequate support in the specification originally filed and therefore comply with the requirements of Section 112. Specifically, a person of ordinary skill in the art would have understood, at the time the application was filed, that the description of embodiments of the invention that “include the consumption of more than one fluid ounce per day” (see Specification, p. 16, ln. 3) inherently include consumption of three fluid ounces per day. Contrary to the Examiner’s assertion, “more than one fluid ounce” necessarily includes three ounces.

The proposition that the Applicant intended “more than 1 oz.” to be read broadly is supported by claim language as-filed in the original application. The claims as-filed in the original specification are part of the disclosure which may be used to support subsequent amendments made to the claims. Where the application as originally filed contains claims disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In Re Benno* 768 F.2d 1340 (Fed. Cir. 1985). Thus, applicant may rely on the claims as originally filed with the specification as support for the

position that “more than 1 fl.oz.” necessarily includes 3 fl. ozs. The MPEP elucidates methodology for determining the adequacy of the written description requirement. The MPEP indicates that claim construction is an essential part of the examination process and that “each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. *In Re Morris* 127 F.3d 1048 (Fed. Cir. 1997). The original disclosure in claims 2 and 10 of the originally filed application indicate that the present invention contemplated a method comprising the step of consuming more than 1 fl. oz. of dietary supplement per day. Following the precedent of *In re Morris* the MPEP indicates that the originally filed claim language must be given the broadest reasonable interpretation. The broadest reasonable interpretation of “more than 1 oz.” may not encompass 100 ounces, but the broadest reasonable interpretation of “more than 1 oz.” necessarily includes 3 ounces. Thus, the claims as originally filed given their broadest possible interpretation support the disclosure in the specification on page 16, line 13, which also indicates that one should “include the consumption of more than 1 fl.oz. per day.” Giving the originally filed claims their broadest possible interpretation does not yield the restrictive assessment that more than 1 fluid ounce does not include 3 fluid ounces, but is congruent with applicant’s argument that “more than 1 fl. oz.” necessarily includes 3 fluid ounces.

In light of the foregoing, Applicant respectfully submits that the rejected claims do not constitute new matter and accordingly requests withdrawal of the Examiner’s rejections of claims 1 and 9 under Section 112.

2. Claim Rejections under 35 U.S.C. § 103(a).

An invention is unpatentable under Section 103 “if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would

have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.”

To establish a *prima facie* case of obviousness, three criteria must be met. “First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” MPEP § 2142. A “clear and particular” showing of the suggestion to combine or modify is required to support an obviousness rejection under Section 103. *Id.* For the reasons set forth below, Applicant submits that the prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner; thus, Applicant’s claims are not obvious in view of the prior art references.

Claims 1, 4-12, 24 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mumford (1998) in view of Brock (1991), Gagnon (1997), and further in view of Nahir (“Nahir”). Specifically, the Examiner indicates that Gagnon indicates taking medical preparations on an empty stomach to increase the preparations effectiveness. The Examiner concludes that an ordinary artisan would have had a reasonable expectation that if *Morinda citrifolia* were taken on an empty stomach that the medicinal effectiveness would have increased. Further, the Examiner indicates that varying quantities of known medicinal preparations is considered optimization of result effective variables, routine in the art of nutritive pharmacology. The Examiner cites Mumford for the proposition that the result of inhibiting, preventing and reversing lipid peroxidation would have occurred due to the ingestion of the juice, and is therefore considered an intrinsic property of the methods disclosed in the prior art. Thus, the

Examiner concludes that the effect of preventing and reversing lipid peroxidation was inherent in Mumford's disclosure.

The prior art references cited by the Examiner alone or in combination with each other do not teach or suggest all the claim limitations of the present invention. Claim 1 recites a method comprising "consuming on an empty stomach each day to inhibit, prevent, and reverse lipid peroxidation, three ounces of a dietary supplement comprising a juice from *Morinda citrifolia* fruit ... and at least one second juice from the group consisting of fruit juice and vegetable juice." First, none of the cited references, alone or in combination with other cited references, discloses or suggests consumption of a *Morinda citrifolia*-containing supplement to inhibit, prevent and reverse lipid peroxidation. Second, none of the cited references, alone or in combination with other cited references, discloses or suggests consuming three ounces of *Morinda citrifolia* juice product. Third, none of the cited references, alone or in combination with other cited references, discloses or suggests combining *Morinda citrifolia* fruit juice and at least one second juice from a group consisting of fruit juice and vegetable juice. Consequently, the present invention is not obvious in view of such references because none of the prior art cited, alone or in combination with each other, teach or suggest all of the claim limitations of the present invention.

First, no cited reference alone or in combination with other cited references discloses or suggests the consumption of *Morinda citrifolia* containing a supplement to inhibit, prevent and reverse lipid peroxidation. Mumford discloses consuming *Morinda citrifolia* fruit juice to treat migraine headaches, increase energy levels and inhibit susceptibility to the common cold. Mumford also discloses topically applying *Morinda citrifolia* leaves to reduce pain. (See

Mumford, p. 1-2). Mumford neither discloses nor suggests consuming *Morinda citrifolia* fruit juice to inhibit, prevent or reverse lipid peroxidation.

A “*prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties.” See MPEP § 2144.09. In this case, the present application indicates consumption of three ounces of a dietary supplement containing *Morinda citrifolia* fruit juice to inhibit, prevent and reverse lipid peroxidation. Such use of *Morinda citrifolia* fruit juice is neither expressly indicated nor suggested by Mumford or any other cited reference. Indeed, Mumford emphasizes consumption of *Morinda citrifolia* fruit juice to reduce the occurrence and/or severity of migraine headaches, among other ailments. In so doing, Mumford teaches away from the present invention. In addition, the present invention comprises unexpectedly advantageous properties in view of Mumford.

Mumford teaches away from the present invention. Migraine headaches are caused by vasoconstriction of blood vessels in the brain, leading to hypoxia of the vascular system. Hypoxia is defined as inadequate oxygenation that causes a deficiency of oxygen in reaching the tissues of the body. Reducing the severity and/or frequency of migraine headaches thus requires increasing oxygenation to reverse hypoxic effects. The present invention, on the other hand, seeks to reduce free radicals in the body, which are caused by oxygenation. Accordingly, the present invention teaches consuming a *Morinda citrifolia*-containing supplement to reduce oxygenation and, hence, the production of free radicals. As the prior art teaches that reducing oxygenation exacerbates migraine headaches, one skilled in the art would not be motivated by Mumford to modify the invention disclosed therein to inhibit, reverse and prevent lipid

peroxidation as claimed by the present invention since reducing oxygenation would vitiate the purpose of Mumford in reducing the frequency and severity of migraine headaches.

Second, no cited reference alone or in combination with other references discloses or suggests consumption of three ounces of a supplement containing *Morinda citrifolia* fruit juice. Mumford fails to disclose or suggest consuming three ounces of a supplement containing *Morinda citrifolia* fruit juice to inhibit reverse and prevent lipid peroxidation, and specifically teaches away from such a dosage by emphasizing the beneficial effects of consuming only one or two ounces of the juice. One skilled in the art would not be motivated by Mumford to consume more than two ounces of the juice where Mumford emphasizes that only one ounce of the juice is sufficient to make one “feel better.” See Mumford, p. 1.

Third, no cited reference discloses or suggests the consumption of a supplement containing *Morinda citrifolia* juice and at least one second juice from the group consisting of fruit juice and vegetable juice. The claims of the present invention have been amended to include the language “and at least one second juice from the group consisting of fruit juice and vegetable juice.” This amendment to the claims finds support in specification. The specification indicates “[t]he supplement may also include other natural juices, such as natural grape juice concentrate and natural blueberry juice concentrate and/or another natural fruit juice.” *Specification* p. 10, ln. 15-17. Because none of the prior art cited by the Examiner discloses or suggests combining *Morinda citrifolia* and at least one second juice, this limitation is not taught by the prior art. Gagnon teaches taking medicinal preparations on an empty stomach to increase preparations effectiveness. Gagnon does not teach combining *Morinda citrifolia* with at least one second juice. Mumford teaches consuming *Morinda citrifolia* containing supplement. Mumford does not suggest combining *Morinda citrifolia* juice and at least one second juice.

Brock teaches the pasteurization of food and beverage products. Brock does not teach combining *Morinda citrifolia* juice and at least one second juice. Finally, Nahir discloses an apparatus for removing pulp from a juice, but does not suggest combining *Morinda citrifolia* juice and at least one second juice. Thus, the prior art cited by the Examiner against the present invention fails to disclose or suggest the consumption of a first juice from *Morinda citrifolia* fruit and at least one second juice from a group consisting of fruit juice and vegetable juice.

As the cited references fail to disclose or suggest all of the present claim limitations, and further fail to suggest modifying the reference as suggested by the Examiner, the present invention is not obvious in view of such references.

Further, as claims 4-12, 24 and 26 depend from otherwise allowable subject matter, such claims are also not obvious in view of the cited references.

Accordingly, Applicant respectfully requests withdrawal of the rejections of claims 1, 4-12, 24 and 26 under Section 103.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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Respectfully submitted,

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